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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE RECEIVED

In re application of

Jose V. Torres

JUL 1 6 2002

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Appln. No.: 10/072,084

Filed: February 8, 2002

For: IMMUNOGENIC FORMULATION AND PROCESS FOR PREPARATION THEREOF

Attorney Docket No.: 3648.032

UNDER 37 C.F.R. §1.97 and §1.98

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

sir:

In accordance with the duty of disclosure under 37 C.F.R. §1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the following documents for the above-identified application, which were cited in the International Search Report. Copies of the documents set forth below and listed on the attached Form PTO-1449 are provided herewith.

- 1. U.S. Patent No. 5,580,563
- 2. U.S. Patent No. 6,110,465
- 3. Meyer, Debra, et. al; Hypervariable Epitope Constructs
 Representing Variability in Envelope Glycoprotein of
 SIV Induce a Broad Humoral Immune Response in Rabbits

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SERIAL NO.: 10/072,084
INFORMATION DISCLOSURE STATEMENT

and Rhesus Macaques; AIDS Research and Human Retroviruses, 1998, 14.9, pp. 751-760

- 4. Puntoriero, Giulia, et al.; Towards a Solution for Hepatitis C Virus Hypervaribility: Mimotopes of the Hypervariable Region 1 Can Induce Antibodies Cross-Reacting With a Large Number of Viral Variants; The EMBO Journal, 1998, 17.13, pp. 3521-3533
- 5. Anderson, David E., et al.; Hypervariable Epitope Constructs As a Means of Accounting for Epitope Variability; Vaccine, 1994, 12.8, pp.736-740
- 6. Meyer, Debra and Torres, Jose V.; Hypervariable Epitope
 Construct: A Synthetic Immunogen That Overcomes MHC
 Restriction of Antigen Presentation; Molecular
 Immunology, 1999, 36, pp. 631-637
- 7. Nardelli, B., et al.; A Chemically Defined Synthetic Vaccine Model for HIV-1; The Journal of Immunology, 1992, 148.3, pp. 914-920
- 8. Prezzi, Caterina, et al.; Selection of Angigenic and Immunogenic Mimics of Hepatitis C Virus Using Sera from Patients; The Journal of Immunology, 1996, 156, pp. 4504-4513
- 9. Lenstra, Johannes A., et al.; Isolation of Sequences From a Random-Sequence Expression Library That Mimic Viral Epitopes, Journal of Immunological Methods, 1992, 152, pp. 149-157

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10. Carlos, Maria P., et al.; Antibodies From HIV-Positive and AIDS Patients Bind to an HIV Envelope Multivalent Vaccine, Journal of Acquired Immune Deficiency Syndromes, 1999, 22, pp. 317-324

- 11. Carlos, Maria P., et al.; Immunogenicity of a Vaccine Preparation Representing the Variable Regions of the HIV Type 1 Envelope Glycoprotein, Aids Research and Human Retroviruses, 2000, 16.2, pp. 153-161
- 12. Jackson, Peter, et al.; Reactivity of Synthetic Peptides representing Selected Sections of Hepatitis C Virus Core and Envelope Proteins With a Panel of Hepatitis C Virus-Seropositive Human Plasma, Journal of Medical Virology, 1997, 61, pp. 67-79
- 13. Gras-Masse, H., et al.; Synthetic Vaccines and HIV-1
 Hypervariability: A "Mixotope" Approach, Peptide
 Research, 1992, 5.4, pp. 211-216

The present Information Disclosure Statement is being filed (1) no later than three months from the application's filing date, or (2) before the mailing date of the first Office Action on the merits and, therefore, no Certification Under 37 C.F.R. §1.97(e) or fee under 37 C.F.R. §1.17(p) is required.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to

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' ATTY. DOCKET: 3648.032

antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Applicant respectfully requests that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-1449 be returned in accordance with MPEP §609.

JUL 16 2002

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Date: July 9, 2002

Respectfully submitted,

Yate K. Qutliff
Registration No. 40,577

CERTIFICATE OF MAILING AND AUTHORIZATION TO CHARGE

I hereby certify that a copy of the foregoing INFORMATION DISCLOSURE STATEMENT, Form PTO-1449, and thirteen references and attachments thereto for U.S. Application No. 10/072,084 filed attachments 8, 2002, were deposited in first class U.S. mail, February 8, 2002, were deposited in first class U.S. mail, postage prepaid, addressed: Attn: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on this the 9th day of July, 2002.

The Commissioner is hereby authorized to charge any additional fees, which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account No. 16-0877.

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INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

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| | Applicant(s) Jose V. Torres | | ENTE | <u></u> |
| | Filing Date February 8, 2002 | Group Art Unit | R 16 | 8 2 |
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U.S. PATENT DOCUMENTS

| EXAMINER | REF | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING E | |
|----------|-------|-----------------|--------------|--------------------------|-------|--------------|----------|---------|
| INITIAL | 1 | 5,580,563 | 12/03/96 | Tam | 424 | 197.11 | | |
| | 2 | 6,110,465 | 08/29/00 | Bukh et al. | 424 | 189.1 | | |
| | | 3,220,000 | | | | | | |
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| | Meyer, Debra, et al.; Hypervariable Epitope Constructs Representing Variability in Envelope Glycoprotein of SIV Induce a Broad Humoral Immune Response in Rabbits and Rhesus Macaques; AIDS Research and Human Retroviruses, 1998, 14.9, pp. 751-760 |
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| | Puntoriero, Giulia, et al.; Towards a Solution for Hepatitis C Virus Hypervaribility: Mimotopes of the Hypervariable Region 1 Can Induce Antibodies Cross-Reacting With a Large Number of Viral Variants; The EMBO Journal, 1998, 17.13, pp. 3521-3533 |

EXAMINER DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

CENTER 1600/29 Application Number Docket Number (Optional) 3648.032 10/072,084 Applicant(s) INFORMATION DISCLOSURE CITATION Jose V. Torres (Use several sheets if necessary) Group Art Unit Filing Date 1646 **February 8, 2002** (Including Author, Title, Date, Pertinent Pages, Etc.) Anderson, David E., et al.; Hypervariable Epitope Constructs As a Means of Accounting for Epitope Variability; Vaccine, 1994, 12.8, pp. 736-740 *EXAMINER INITIAL 5 Meyer, Debra and Torres, Jose V.; Hypervariable Epitope Construct: A Synthetic Immunogen That Overcomes MHC Restriction of Antigen Presentation; Molecular Immunology, 1999, 36, pp. 631-637 6 Nardelli, B., et al.; A Chemically Defined Synthetic Vaccine Model for HIV-1; The Journal of Immunology, 1992, 148.3, pp. 914-920 7 Prezzi, Caterina, et al.; Selection of Antigenic and Immunogenic Mimics of Hepatitis C Virus Using Sera from Patients; The Journal of Immunology, 1996, 156, pp. 4504-4513

Lenstra, Johannes A., et al.; Isolation of Sequences From a Random-Sequence Expression Library That Mimic Viral Epitopes, Journal of Immunological Methods, 1992, 152, pp. 149-157

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Envelope Glycoprotein, Aids Research and Human Retroviruses, 2000, 16.2, pp. 153-161

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not considered. Include copy of this form with next communication to applicant.

Carlos, Maria P., et al.; Antibodies From HIV-Positive and AIDS Patients Bind to an HIV Envelope Multivalent Vaccine,

Carlos, Maria P., et al.; Immunogenicity of a Vaccine Preparation Representing the Variable Regions of the HIV Type 1

Jackson, Peter, et al.; Reactivity of Synthetic Peptides Representing Selected Sections of Hepatitis C Virus Core and Envelope Proteins With a Panel of Hepatitis C Virus-Seropositive Human Plasma, Journal of Medical Virology, 1997, 61, pp 67-79

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